

**Assessment of the USEPA Region 4
Laboratory Certification Program for Drinking Water**

Conducted by the

**Office of Water
Office of Ground Water and Drinking Water
Technical Support Center**

Date of Evaluation: October 21 – 23, 2015

Date of Report: November 16, 2016

**U. S. ENVIRONMENTAL PROTECTION AGENCY
Cincinnati, Ohio 45268**

Introduction

The Manual for the Certification of Laboratories Analyzing Drinking Water¹, Supplement 1², and Supplement 2³ (hereafter collectively referred to as MCLADW) require the Office of Ground Water and Drinking Water (OGWDW) to "review the EPA Regional [drinking water] certification programs annually and evaluate the resources and personnel available in each Region to carry out the certification program." To meet this requirement paper assessments in the form of questionnaires are performed annually and onsite assessments are conducted triennially.

Primacy states maintain programs for the certification and/or accreditation of laboratories conducting analyses of drinking water compliance samples per federal regulations [40 CFR 142.10(b)(3)(i)]. The region oversees the Principal State Laboratory (PSL) or PSL network of laboratories in every state that holds primacy. The laboratories may be EPA-certified, National Environmental Laboratory Accreditation Program (NELAP)-accredited or recognized through a reciprocity agreement with another laboratory certification program (LCP). If the PSL performs all of the analyses for all regulated drinking water contaminants for the state, a State Drinking Water Certification/Accreditation Program is not required as no commercial or municipal laboratories are involved. If the PSL performs some but not all analyses for all regulated drinking water contaminants for the state, a State Drinking Water Laboratory Certification/Accreditation Program is required in which commercial or municipal laboratories are certified, accredited or recognized through reciprocity by the state program. The region holds primacy for all non-primacy states (tribes) and certifies/accredits or recognizes through reciprocity all laboratories used by them. EPA Region 4 oversees the PSL/PSL network in 8 primacy states.

The regional laboratory certification program assessment (RLCPA) took place between October 21 and 23, 2015 at the Region 4 laboratory in Athens, GA. The OGWDW TSC audit team consisted of Dr. Judy Brisbin (TSC), Michella Karapondo (TSC), and K. Erina Keefe (The Cadmus Group, Inc. [Cadmus]). See Attachment A for a detailed agenda, and Attachment B for a summary of attendees at the opening conference, file review, presentation of the drinking water update, and exit debrief.

1. Assessment Summary

a. Commendations

The following items are outstanding actions/practices taken by the program in Region 4 in support of the LCP.

1. Although Region 4 consists of more states than any other EPA region, timely State Laboratory Certification Program Assessments (SLCPAs) are conducted on a triennial schedule.

¹ Manual for the Certification of Laboratories Analyzing Drinking Water, Fifth Edition, 2005, EPA 815-R-05-004.

² Supplement 1 to the Fifth Edition of the Manual for the Certification of Laboratories Analyzing Drinking Water, Supplement 1 to EPA 815-R-05-004, June 2008, EPA 815-F-08-006.

³ Supplement 2 to the Fifth Edition of the Manual for the Certification of Laboratories Analyzing Drinking Water, Supplement 2 to EPA 815-R-05-004, 2012, EPA 815-F-12-006.

2. SOPs are reviewed and updated regularly, and are comprehensive.
3. In general, Region 4 maintains strong communication with their states. Communication between the regional certification officers (COs) and states is logged in a spreadsheet, updated weekly, and amended with any technical assistance, including SLCPAs, PSL audits, and proficiency tests (PTs).
4. The annual certificates sent to states include a cover sheet identifying requirements (triennial audits and successful PTs), notable certification changes, and a table displaying status by analyte and method. Region 4 goes above and beyond by including Region 4 Drinking Water Proficiency Testing Sample Policies in this report. If an analyte is not certified, Region 4 clearly identifies the analyte in bold text and explains why in the cover page and analyte table.
5. The document management spreadsheet records dates for audits, reports, corrective actions, responses, and acceptance (close-out) letters, as well as scheduling goals to complete these items.

b. Recommendations/Action Items

The following items are suggested action items aimed at strengthening the program in Region 4. These items are not deficiencies and do not require corrective actions; they are simply suggestions.

Repeat Recommendation(s)

1. Region 4 should ensure that regional and state COs audit the training course every five years. Region 4 should follow up with COs to ensure they attend as soon as possible if it has been longer than five years since they've attended.

New Recommendation(s)

1. Seven state principle satellite labs are currently not certified by Region 4. TSC understands that Region 4 was not informed of these satellite labs until recently, and that upon learning of the labs the region followed up for PT study results. Region 4 plans to loop these audits into the triennial cycle, which means that some labs will not be certified directly by Region 4 until 2017. Given that time gap, TSC encourages Region 4 to audit these labs as soon as possible. The region currently requires that the satellite labs submit PT study results to Region 4.
2. Currently there is only one CO certified for microbiology and *Cryptosporidium*. For redundancy, the region should ensure a back-up CO is available for those fields.
3. Region 4 should develop a continuity plan to address radiochemistry audits, ensuring the correct documentation is available.
4. Region 4 should continue to update and organize their filing system. If Region 4 will transition to a fully electronic filing system, at a minimum, memoranda of understanding (MOU) or email correspondence between the PSL and commercial lab should be filed in the appropriate state's files.

5. As part of the SLCPA, Region 4 is encouraged to routinely observe the state program COs/assessors performing an onsite laboratory audit. The SOP should be updated to include this practice.
6. The Region 4 LCP team should continue to foster the relationship with the Region 4 Drinking Water Program (DWP) in the Water Management Protection Division. While Region 4 currently includes the DWP on report submittals, the region should also consider inviting DWP to attend State Program calls.
7. The region should continue to standardize terminology to describe program effectiveness in SLCP certification reports. For minimally or marginally effective SLCPs, or for SLCPs deemed to not be effective, a close-out letter upgrading the certification status should be submitted to the state once corrective actions have been implemented and approved.
8. Since email is now the most common form of communication, the region should replace fax templates in SOPs with email templates.

c. Findings/Corrective Actions

The following items are considered deficiencies in the Region 4 program and require corrective action; corrective actions must be submitted to OGWDW and documented upon completion (number the items).

Repeat Finding(s)

None.

New Finding(s)

1. Primacy states are required to use laboratory facilities certified by the region and capable of performing analytical measurements of all contaminants specified in state primary drinking water regulations (40 CFR 142.10(b)(4)). Currently, no states in Region 4 have an official agreement to address asbestos and dioxin. Region 4 could identify certified commercial labs for asbestos and dioxin and encourage states to develop an agreement with those labs. If waivers for asbestos and dioxin are in place, copies of the waivers should be added to the states' files.

2. EPA Region 4 Laboratory Certification Program Overview

Personnel involved in the Region 4 Drinking Water (DW) LCP are included in Table 1. For regional COs, their areas of responsibility and training status are also included. See Attachment C for an organization chart of the Science and Ecosystem Support Division (SESD).

Table 1. Regional Laboratory Certification Program Personnel					
Title	Name Office/Branch	Area(s) of Responsibility	Year Passed EPA CO Training	Year Last Audited EPA CO Training	Year last audit was conducted
Regional Administrator	Heather McTeer Toney Sam Nunn Atlanta Federal Center 61 Forsyth Street, SW Atlanta, GA 30303.S. (404) 562-9900	-----			
Regional Certification Authority	Mike Peyton, Director U. S. EPA, Region 4 SESD 980 College Station Road Athens, Georgia 30605 Peyton.Mike@epa.gov (706) 355-8544	-----			
Regional Lab Cert Program Manager	Vacant				
Regional Laboratory Director	Danny France, Analytical Support Branch Chief SESD address above France.Danny@epa.gov (706) 355-8738				
Regional Certification Officer	Ray Terhune, CO SESD address above Terhune.Ray@epa.gov (706) 355-8557	Organic Chemistry Inorganic Chemistry	2006	2011	2016
	Denise Goddard, CO SESD address above Goddard.Denise@epa.gov (706) 355-8568	Organic Chemistry Inorganic Chemistry	1998	2011	2012
	Nancy Seabolt, CO SESD address above Seabolt.Nancy@epa.gov (706) 355-8687	Organic Chemistry Inorganic Chemistry	2012		2016
	Viola Reynolds, CO SESD address above Reynolds.Viola@epa.gov (706) 355-8569	Microbiology <i>Cryptosporidium</i>	2010		2016
	John Thomason, PhD, CO SESD address above Thomason.John@epa.gov (706) 355-8771	Inorganic Chemistry	2013		2015
	Sandra Aker, CO SESD address above Aker.Sandra@epa.gov (706) 355-8772	Inorganic Chemistry	2015		2015
	Jeffrey Wilmoth, Chemist SESD address above Wilmouth.Jeffrey@epa.gov (706) 355-8623	Organic Chemistry New employee 8/24/15	Attending 2016		

3. State Laboratory Certification Program Assessments

The regions oversee SLCPs. As stated in the MCLADW, the regions' responsibilities include performing "an annual review of state/tribal certification programs and proficiency testing results and monitor the adequacy of state/tribal programs for certifying laboratories." This section reviews the documents and procedures used by the region to perform these tasks (Table 2).

a. Review of Regional Standard Operating Procedures for Assessing Primacy State Drinking Water Certification/Accreditation Programs

- The SOP for Quality System Assessment of the Region 4 states responsible for Implementing a Drinking Water Certification Program (SOP No: QAS-SOP-003) is current, document controlled, and contains signature approval indicating that it has been both reviewed and approved by management. The SOP is reviewed annually, and was last updated in September 2014.
- The SOP contains the administrative/programmatic elements listed in EPA-QA/G-6 (Title page, Table of contents, Procedures, Checklists, Quality control, and References).

b. Regional Personnel Qualifications/Responsibilities for Assessing Primacy State Drinking Water Certification/Accreditation Programs

- The SOP (QAS-SOP-003) clearly defines the required qualifications, roles and responsibilities of members of the regional assessment team. It includes a requirement to attend a TSC certification class and regular refresher classes. Although the SOP requires attendance to regular refresher classes, one CO is overdue to attend a refresher class.
- Staffing concerns
 - Currently, there are four regional COs that are certified for chemistry, but only Viola Reynolds is certified for microbiology and *Cryptosporidium*. Region 4 would benefit from additional staff certified for microbiology and possibly an additional for *Cryptosporidium*. There is no CO for radiochemistry; the region utilizes the EPA radiochemistry contractor.
 - Ray Terhune is acting as the LCPM while Ms. Maycock is on detail, adopting additional responsibilities without the ability to shift his current duties to other staff. Region 4 does not have a contingency plan for a full-time LCPM in case Ms. Maycock does not return to OQA. Ms. Maycock has been on detail for more than one year, and it is uncertain as to whether or not she will return to her position. In addition to succession planning, Region 4 is encouraged to identify someone as a more long term replacement while Ms. Maycock is on detail.

Table 2. State Laboratory Program Assessments

Primacy State	State Laboratory Certification Program Assessments				Number of Laboratories Certified/Accredited				
	Agency	Assessor	Date of last SLCPA	Date of last signed certificate/report	In State (Out of State)				
					Chemistry	Microbiology	Radiochemistry	<i>Cryptosporidium</i>	Asbestos
AL	ADEM Montgomery, AL	EPA Region 4	September 9, 2014	April 14, 2015	12 (18)	35 (1)	0 (8)	2(2)	0 (2)
FL	FDOH Jacksonville, FL	EPA Region 4	October 28, 2014	June 19, 2015	92 (53)	146 (18)	6 (18)	0 (1)	3 (5)
GA	GAEPD Atlanta, GA	EPA Region 4	December 13, 2013	October 22, 2014	5 (23)	80 (5)	0 (12)	0 (2)	1(2)
KY	KYDEP Frankfort, KY	EPA Region 4	April 28, 2015	June 17, 2015	13 (27)	46 (3)	0 (10)	1 (3)	1 (2)
MS	MSDH Jackson, MS	EPA Region 4	April 22, 2013	January 22, 2014	2 (10)	5(6)	0	0	0(1)
NC	NCSLPH Raleigh, NC	EPA Region 4	June 11, 2013	August 26, 2013	83(41)	189 (21)	3 (9)	1(6)	3 (5)
SC	SCDEC Columbia, SC	EPA Region 4	August 27, 2015	November 10, 2015	187 (5)	117 (6)	1 (3)	0 (5)	0 (3)
TN	TDEC Nashville, TN	EPA Region 4	June 2, 2015	Open, pending re-visit	18 (16)	136 (7)	4 (7)	0 (3)	0 (3)

- Funding was reduced in 2015, which caused a reduction in the number of COs that could travel to each audit. In addition, the travel budget was reduced in 2015 which limited the number of uncertified satellite laboratories that could be assessed. These budgetary constraints limited the region's ability to assess all required elements of PSLs and SLCPAs, and hindered the region from auditing uncertified satellite laboratories.

c. Regional Procedures for Assessing Primacy State Drinking Water Certification/Accreditation Programs

- The SOP describes procedural steps for the regional oversight of primacy SLCPs based on the MCLADW.
- The SOP describes procedures for the regional oversight of SLCPs based on third-party accrediting bodies, including the right to override accreditation decisions, though the SOP does not explicitly name the NELAC Institute (TNI) (NELAP ABs). Region 4 performs independent assessments of NELAP ABs. The SOP requires regional assessors to determine adequate recordkeeping procedures and documentation at the SLCP. The procedure for reviewing an annual program audit report is discussed in detail in the SOP.
- Region 4 has produced an independent SOP (SOP No.: QAS-SOP-005) solely for the purpose of describing procedures for the issuance of the report by the region to SLCPs, and any needed follow-up/corrective actions. Region 4 should include instructions to send a close-out letter to the SLCP once corrective actions are implemented and approved, and upgrade the SLCP certification status, if needed.
- Region 4 onsite assessments of SLCPs are performed triennially, and are current. This is a significant accomplishment due to the large number of states in Region 4.
- Region 4 does not participate on the TNI AB evaluation teams. Region 4 assesses the programs in Florida independently.
- The area(s) of responsibility and training status of each CO used by each primacy state in Region 4 are listed in Table 3. Florida currently uses third-party auditors to perform audits, and directly observes ten percent of on-site assessments conducted by each contract provider. The process is new, but the state has a Contract Oversight SOP and Checklist designed to promote consistency and freedom from conflicts of interest (COI). Georgia has one state CO; chemistry and radiochemistry labs are certified by reciprocity with FDOH. Records include documentation of a Memorandum of Agreement (MOA) for radiochemistry with FDOH.
- Fifteen state COs are past due to audit an EPA CO training as of the 2015 Annual Questionnaire. Eleven COs have never audited the CO training in their certified field. Region 4 should encourage the state COs to attend the refresher training as possible.
- Region 4 states consider staffing adequate to complete required assessments, with the exception of South Carolina, which needs additional COs for radiochemistry and organic chemistry.

Table 3: Area of Responsibility and Training Status of Certification Officers Utilized by Primacy States				
Name/Affiliation	State	Area(s) of Responsibility	Year Passed EPA CO Training	Year Last Audited EPA CO Training
Angelica B. Webb, ADPH	AL	Microbiology	2003 Micro	2011 Micro
Ashley Megelin, ADPH	AL	Microbiology	2013 Micro	
Olivia Toole, ADPH	AL	Microbiology	2015 Micro	
Rip Starr, ADEM	AL	Chemistry	1998 Chemistry	2010 Chemistry
Latoya Wright, ADEM	AL	Chemistry	2010 Chemistry	
Carl C. Kircher, Ph. D, FDOH	FL	Chemistry Microbiology Radiochemistry	1993 Chemistry. 1993 Micro 2006 RAD	2014 Chemistry 2014 Micro
Vanessa Soto-Contreras, FDOH	FL	Chemistry Microbiology	1994 Chemistry 1991 Micro	
Michael Shepherd Shepherd Technical Services, Laboratory Accreditation Bureau	FL	Chemistry Microbiology Cryptosporidium	2012 Chemistry 2012 Micro 2015 Crypto	
Mei Beth Shepherd Shepherd Technical Services, Laboratory Accreditation Bureau	FL	Chemistry Microbiology Cryptosporidium	2012 Chemistry 2012 Micro 2015 Crypto	
Michael Hintz Shepherd Technical Services, Laboratory Accreditation Bureau	FL	Chemistry Microbiology	2015 Chemistry 2014 Micro	
Mary Wehbe Shepherd Technical Services, Laboratory Accreditation Bureau	FL	Chemistry Microbiology	2013 Chemistry 2014 Micro	
Jack Farrell Analytical Excellence, Inc.	FL	Chemistry Microbiology	2012 Organic Chem 2014 Inorganic Chem 2012 Micro	
Patty Snyder Analytical Excellence, Inc.	FL	Chemistry Microbiology	2012 Chemistry 2011 Micro	
Paul LeBlanc Analytical Excellence, Inc.	FL	Chemistry Microbiology	2009 Chemistry 2009 Micro	
Jeanne Mensingh Dade Moeller and Associates, Inc.	FL	Chemistry Microbiology	2012 Chemistry 2015 Micro	
Mitzi Miller Dade Moeller and Associates, Inc., American Association for Laboratory Accreditation	FL	Chemistry Microbiology	1994 Chemistry 2004 Micro	2005 Chemistry
John Gumper Dade Moeller and Associates, Inc., American Association for Laboratory Accreditation	FL	Chemistry Microbiology	2014 Chemistry 2014 Micro	
Richard Sheibley Dade Moeller and Associates, Inc., American Association for Laboratory Accreditation	FL	Chemistry Microbiology Radiochemistry	1998 Chemistry 1998 Micro 2006 RAD	
Nile Luedtke Dade Moeller and Associates, Inc., American Association for Laboratory Accreditation	FL	Chemistry Microbiology	2012 Chemistry 2012 Micro	

Table 3: Area of Responsibility and Training Status of Certification Officers Utilized by Primacy States

Name/Affiliation	State	Area(s) of Responsibility	Year Passed EPA CO Training	Year Last Audited EPA CO Training
Fred Ordway Dade Moeller and Associates, Inc.	FL	Chemistry Microbiology	2012 Chemistry 2012 Micro	
Michelle Wade Wade Consulting and Solutions	FL	Chemistry Microbiology	2009 Chemistry 2009 Micro	
Matt Sica ANSI National Accreditation Board	FL	Chemistry Microbiology Cryptosporidium	2004 Chemistry 2004 Micro 2011 Crypto	
Shannon Swantek ANSI National Accreditation Board	FL	Chemistry Microbiology	2009 Chemistry 2012 Micro	
Tom McAninch Shepherd Technical Services, Laboratory Accreditation Bureau	FL	Microbiology	2015 Micro	
Richard Strickert Laboratory Accreditation Bureau	FL	Inorganic Chemistry	2014 Inorganic Chem	
Louis Wales Wales Scientific Solutions	FL	Chemistry Microbiology	1989 Chemistry 2015 Micro	
Lynne Grubb GA EPD	GA	Chemistry Microbiology Cryptosporidium	2013 Inorganic Chem 2014 Organic Chem 2011 Micro 2013 Crypto	
Frank Hall KYDEP/DOW	KY	Chemistry Microbiology	2007 Chemistry 2007 Micro	2015 Chemistry 2015 Micro
Patrick Garrity KYDEP/DOW	KY	Chemistry Microbiology Cryptosporidium Radionuclides	2007 Chemistry 2007 Micro 2010 Crypto - - - RAD	2015 Chemistry 2015 Micro
Kevin Stewart KYDEP/DOW	KY	Chemistry Microbiology Cryptosporidium	2009 Chemistry 2011 Micro 2013 Crypto	2015 Chemistry 2015 Micro
Erich Cleaver KYDEP/DOW	KY	Inorganic Chemistry Microbiology	2014 Inorganic Chem 2014 Micro	
Tiffany Nolan KYDEP/DOW	KY	Microbiology	2014 Micro	
Ted Pass, Ph. D KYDEP/DOW	KY	Microbiology	2000 Micro	2015 Micro
Jack Wiedo – resigned 9/2015 KYDEP/DOW	KY	Microbiology	2015 Micro	
Samantha Kaiser KYDEP/DOW	KY	Chemistry	2015 Chemistry	
Wanda Ingersoll MSPHL	MS	Chemistry	1994 Chemistry	2013 Chemistry
Brian Castleberry MS PHL	MS	Chemistry	2002 Chemistry	2015
Lesia Harris MS PHL – not doing audits in 2016	MS	Chemistry	2014 Chemistry	
Janet Hartin MS PHL	MS	Chemistry Microbiology	2014 Chemistry 2015 Micro	
Monica Mitchell MS PHL	MS	Microbiology	2011 Micro	

Table 3: Area of Responsibility and Training Status of Certification Officers Utilized by Primacy States				
Name/Affiliation	State	Area(s) of Responsibility	Year Passed EPA CO Training	Year Last Audited EPA CO Training
Reginald Wood MS PHL	MS	Microbiology	2014 Micro	
Phyllis Givens MS PHL	MS	Microbiology	1993 Micro	2012 Micro
Chris Goforth NC SLPH	NC	Chemistry Microbiology Radiochemistry	2008 Chemistry 2006 Micro ---- RAD	
Michele Sartin NC SLPH (formerly Michele Andrews)	NC	Chemistry Microbiology Radiochemistry (Uranium by ICP-MS)	2013 Chemistry 2012 Micro --- RAD	
David Livingston NC SLPH	NC	Chemistry Microbiology Radiochemistry (Uranium by ICP-MS)	2012 Chemistry 2013 Micro --- RAD	
Cindy Price NC SLPH Manager	NC	Chemistry Microbiology Radiochemistry	2006 Chemistry 2000 Micro ----- RAD	
Carol F Smith SC DHEC	SC	Chemistry Microbiology Radiochemistry	1987 Chemistry 1987 Micro ---- RAD	2011 Chemistry 2009 Micro
Susan E Butts SC DHEC	SC	Chemistry Microbiology	2006 Chemistry 2006 Micro	2012 Chemistry Nominated 2016
Alfred Baquiran SC DHEC	SC	Chemistry Microbiology	2003 Chemistry 2003 Micro	2008 Chemistry 2009 Micro
Bennie Cockerel SC DHEC	SC	Chemistry Microbiology Cryptosporidium	2005 Chemistry 2005 Micro 2010 Crypto	2011 Chemistry Nominated 2016
James Berry SC DHEC	SC	Chemistry Microbiology	2007 Chemistry 2007 Micro	Nominated 2016
Nydia Burdick SC DHEC	SC	Chemistry Microbiology Radiochemistry	2004 Chemistry 2005 Micro	2010 Chemistry 2013 Micro
Paul Miller SC DHEC	SC	New Employee 7/15	Nominated 2016	
Craig La Fever TDEC Retired 2016	TN	Chemistry Microbiology Radiochemistry	2006 Chemistry 2006 Micro 2010 RAD	2012 Chemistry
Prasad Subbanna TDEC	TN	Chemistry Radiochemistry	2006 Chemistry 2006 RAD	2015 Chemistry 2011 RAD
Amy P. Francis TDEC	TN	Microbiology	2006 Micro	2015 Micro
Will Pride TDEC	TN	Microbiology	2009 Micro	2015 Micro

- In the SLCPA report, the region reviews and comments on the state approach to manage and track PTs.
- In May 2014 the Georgia LCP was determined to be “minimally effective” in certifying labs for drinking water analysis. The Mississippi LCP was not determined to be effective, as of August 2013. While the states had addressed findings with corrective actions, no official close-out letters were sent upgrading the certification status of these SLCPs. In July 2015, the Tennessee LCP was determined to be “marginally effective.” Region 4 should standardize terminology of certification levels.
- The SOP is useful, providing several templates for the regional oversight of primacy SLCPs, including a SLCPA checklist, opening and exit sign-in sheets, and an example of a fax to confirm the on-site SLCP. To improve the usefulness of the SOP, Region 4 should consider replacing fax templates with email templates.

d. Regional Records Management for Assessing State Drinking Water Certification Programs

- Records for SLCPA reviews should be maintained in an easily accessible, central location for a period of three years to include the last two on-site audits. The region maintains excellent records. Binders (called “working folders”) are organized by state and include clearly labeled sections for audit reports, PT study results, correspondence, and QMPs. The Audits section contains signed files for the original report, which describes both the lab audit and SLCPA, and corrective actions by the state. Region 4 should ensure that an official close-out letter is submitted to the state once all corrective actions are implemented and approved. This letter should contain any updates to the SLCP certification status, especially if the program is deemed not to be effective in the initial signed report.
- The SOP contains a Record Keeping section, which outlines steps for Region 4 to ensure that (hard copy or electronic) records of chemical analyses are maintained for an appropriate length of time and records are kept until the next certification data audit. The region proactively requests and reviews an annual program report. While the SOP does not explicitly address other documentation, such as correspondence, Region 4 regularly maintains a spreadsheet logging correspondence between regional COs and states.
- The SLCPA reports are thorough, and describe observations of the state’s procedures to conduct on-site inspections as well as findings and corrective actions. The signed letter awards certification pending adequacy of corrective actions to address findings and recommendations. Effectiveness is described as “minimally/marginally effective” for LCPs that need improvement. Responses from the state are also included in the files, including attachments that provide evidence of corrective actions.
- Region 4 maintains files on their network and in hard copy, including annual questionnaires and SLCPAs. The region is transitioning toward electronic record keeping, and other documentation, such as email correspondence, is stored on the network.

- The document management spreadsheet records dates for audits, reports, corrective actions, responses, and acceptance (close-out) letters, as well as scheduling goals to complete these items (e.g., send SLCPA report to the state within 45 days). Region 4 is encouraged to send a final close-out letter once all findings have been addressed after a SLCPA.
- NELAP assessments are not recorded with the regional files, though Region 4 conducts independent assessments for NELAP ABs.

4. Principal State Laboratory Audits

The regions oversee the certification of some laboratories. As stated in the MCLADW, “Regional certification officers are responsible for the certification of the Principal State Laboratory in each Primacy State, and are also responsible for certifying all Tribal Nation laboratories and laboratories in non-Primacy States.” This section reviews the documents and procedures used by the region to perform these tasks.

a. Review of Regional Standard Operating Procedure for Auditing Principal State and Non-Primacy State Laboratories

- The SOP for Quality System Assessment of the Region 4 states responsible for Drinking Water Laboratory Certification (SOP No: QAS-SOP-001) is current, document controlled, and contains signature approval indicating that it has been both reviewed and approved by management. The SOP is reviewed annually, and was last updated in September 2014.

b. Regional Personnel Qualifications/Responsibilities for Auditing Principal State and Non-Primacy State Laboratories

- The SOP clearly defines required qualifications, roles and responsibilities of members of the audit team, describing the education and experience requirements of auditors.
- PSLs are audited on-site triennially; however, Region 4 has recently learned of nine smaller satellite labs, seven of which are overdue for an audit. The region has a plan to rotate the 7 labs into the triennial schedule. In the interim, the satellite labs are certified through their PSL, and PT study results are reviewed by the region.
- As described in the staffing concerns for LCP oversight, staffing and resources are not adequate to oversee all laboratories.

c. Regional Procedure for Auditing Principal State and Non-Primacy State Laboratories

- The SOP describes in detail how the region will certify PSLs in primacy states, and includes criteria for downgrading certification status, provisional certification, revoking certification, and upgrading/reinstating certification.
- The SOP accepts NELAP accreditation as equivalent to EPA certification, adding that Region 4 has the right to audit/assess NELAP-accredited state laboratories regardless

of their accreditation status with NELAP. Region 4 does not participate on TNI AB evaluation teams but conducts an independent assessment.

- The SOP does not describe procedures for recognizing laboratories through reciprocity. Several states contract analysis of select drinking water contaminants. Usually these contaminants are not frequently requested thus capability is not maintained by the lab. Georgia contracts all chemistry contaminants due to staffing issues, and the state has an MOA with FDOH.
- The SOP describes the on-site audit procedure for regulated contaminants generally, and references the MCLADW and specific analytical methods for evaluating the laboratory for compliance. Attachments B and C of the SOP are templates to help the auditor track methods used for each regulated chemistry and microbiology contaminant.
- Region 4 maintains an Excel spreadsheet that manually tracks 95 analytes for each Region 4 state. Annually, Region 4 distributes a PT summary sheet of all regulated contaminants to each state with the status of certified, provisionally certified or not certified. This summary also includes a policy that labs should follow in analyzing and reporting PT study results. If there were two consecutive PT failures for an analyte, the status would be downgraded to provisionally certified or not certified, depending on the previous history. The current approach is effective. Criteria for certification status based on PT study results are included in the SOP.
- The region maintains a document management system in Excel to track audits. The spreadsheet shows the schedule and budget for each audit, the timeframe for the pre-visit package, report, and corrective actions.
- The annual certificates sent to states include a cover sheet identifying requirements (triennial audits and successful PTs), notable certification changes, and a table displaying status by analyte and method. Region 4 goes above and beyond by including Region 4 Drinking Water Proficiency Testing Sample Policies in this report. If an analyte is not certified, Region 4 clearly identifies the analyte in bold text and explains why in the cover page and table (e.g., one method may be used for screening, but in the case of a positive sample result, a different method must be used).

Table 4: Principal State Laboratories in Primacy States and Laboratories in Non-Primacy States

State/Territory/ Tribe/Other ¹	Laboratory Name and Location	Laboratory Type ²	Certification/Accreditation Entity and Date of Most Recent On-site Audit ³			
			CHEMISTRY	MICROBIOLOGY	RADIOCHEMISTRY	CRYPTOSPORIDIUM
<i>AL</i>	<i>Alabama Dept. of Environmental Management Field Operations Division (chemistry) Alabama Department of Public Health (micro) Montgomery, AL</i>	<i>PSL</i>	<i>9/9/14</i>	<i>9/9/14</i>	<i>Present contract Eberline</i>	
<i>FL</i>	<i>Florida Department of Health, Bureau of Public Health Laboratories Jacksonville, FL</i>	<i>PSL</i>	<i>10/28/14</i>	<i>10/28/14</i>	<i>MOA with SC DHEC RAD lab</i>	
<i>GA</i>	<i>Georgia Environmental Protection Division Norcross, GA</i>	<i>PSL</i>	<i>11/18/13</i>	<i>11/18/13</i>	<i>Present contract Pace-Pittsburgh 3/22/16 by TSC</i>	<i>8/19/13</i>
<i>KY</i>	<i>Kentucky Environmental Services Branch Frankfort, KY</i>	<i>PSL</i>	<i>4/28/15</i>	<i>4/28/15</i>	<i>Present contract TestAmerica- St. Louis</i>	
<i>MS</i>	<i>Mississippi Public Health Laboratory, Mississippi State Department of Health Jackson MS</i>	<i>PSL</i>	<i>4/22/13</i>	<i>4/22/13</i>	<i>Present contract Eurofins Eaton Analytical</i>	
<i>NC</i>	<i>North Carolina State Laboratory of Public Health Raleigh, NC</i>	<i>PSL</i>	<i>6/11/13</i>	<i>6/11/13</i>	<i>Present contract Eurofins Eaton Analytical</i>	
<i>SC</i>	<i>Analytical Radiological and Environmental Services Division Columbia SC</i>	<i>PSL</i>	<i>8/25/15</i>	<i>8/25/15</i>	<i>12/3/13 by TSC</i>	
<i>TN</i>	<i>Tennessee Department of Health Division of Laboratory Services Nashville, TN</i>	<i>PSL</i>	<i>6/2/15</i>	<i>6/2/15</i>	<i>9/23/14 by TSC</i>	

Table 4: Principal State Laboratories in Primacy States and Laboratories in Non-Primacy States

State/Territory/ Tribe/Other ¹	Laboratory Name and Location	Laboratory Type ²	Certification/Accreditation Entity and Date of Most Recent On-site Audit ³			
			CHEMISTRY	MICROBIOLOGY	RADIOCHEMISTRY	CRYPTOSPORIDIUM
<i>Cherokee Tribe</i>	<i>Eastern Band of Cherokee Tribal Utilities Cherokee, NC</i>	<i>Tribal</i>	<i>7/23/13</i>	<i>7/23/13</i>		
<i>AL</i>	<i>Alabama Department of Public Health Mobile AL</i>	<i>State Regional lab</i>		<i>5/12/15</i>		
<i>FL</i>	<i>Florida Department of Health, Bureau of Public Health Laboratories Miami FL</i>	<i>State Regional lab</i>		<i>2/2/16</i>		
<i>FL</i>	<i>Florida Department of Health, Bureau of Public Health Laboratories Tampa, FL</i>	<i>State Regional lab</i>		<i>9/15/15</i>		
<i>SC</i>	<i>SC DHEC Charleston, SC</i>	<i>State Regional lab</i>		<i>4/12/16* * scheduled</i>		
<i>SC</i>	<i>SC DHEC Beaufort, SC</i>	<i>State Regional lab</i>		<i>4/13/16* * scheduled</i>		
<i>SC</i>	<i>SC DHEC Greenville, SC</i>	<i>State Regional lab</i>	<i>12/04/12</i>	<i>12/04/12 FY 18</i>		
<i>SC</i>	<i>SC DHEC Aiken, SC</i>	<i>State Regional lab</i>	<i>4/27/09</i>	<i>4/27/09 FY 19</i>		
<i>SC</i>	<i>SC DHEC Florence, SC</i>	<i>State Regional lab</i>	<i>4/21/09</i>	<i>4/21/09 FY 20</i>		
<i>SC</i>	<i>SC DHEC Lancaster, SC</i>	<i>State Regional lab</i>		<i>FY 17</i>		
<i>SC</i>	<i>SC DHEC Myrtle Beach, SC</i>	<i>State Regional lab</i>		<i>FY 17</i>		
<i>TN</i>	<i>TDOH Division of Lab Services Knoxville, TN</i>	<i>State Regional lab</i>		<i>FY 17</i>		

- Region 4 DW laboratories do not have the capacity or capability to analyze for asbestos or dioxin. Region 4 has not identified any laboratory capacity or capability issues regarding laboratories certified by the state for any of the regulated drinking water contaminants, despite that Georgia has less than one full-time CO and contracts out all chemistry contaminants. In Tennessee, organic chemistry contaminants are contracted due to low demand.
- Region 4 consults with the PSLs on all chemistry, microbiology, and radiochemistry contaminants. Before the audit, PSLs will update the region on contaminants that are analyzed and by whom. Region 4 performs the onsite audits for the contract labs, if utilized, in the same manner as the PSLs. However, if some contract labs are not within the region, PT studies and any other certifications are reviewed. The region plans to audit these labs on the triennial schedule, and in the meantime they are included under the certification of the PSL. PT study results have been completed by all satellite labs.
- The cover page of the audit report announces the certification status for the lab in bold text. Expiration dates to the certification status are not included (and are not required). Certification by methods and individual contaminant are included in tables in the report.
- Two of the laboratories certified by the region are overdue for a triennial audit. Region 4 attributes the delay to the addition of newly identified labs. To address the problem, Region 4 plans to assess the 2 overdue labs in 2015, and rotate the remaining labs into the triennial cycle.
- The SOP provides templates for the regional oversight of PSLs and non-primacy state laboratories, including criteria, checklists or other standards that are to be applied during the procedure. There are five example attachments in the SOP (QAS-SOP-001) as well as a separate SOP for developing the audit report (QAS-SOP-005).

d. Regional Records Management for Auditing Principal State and Non-Primacy State Laboratories

Records for on-site laboratory assessments of PSLs and non-primacy state laboratories should be maintained in an easily accessible central location for a period of three years to include the last two on-site audits, or longer if required by specific state regulations.

- The SOP addresses record management requirements for the regional oversight of PSLs and non-primacy state laboratories (e.g., retention and locations of regional files). The location is identified (i.e., working files section of the Quality Assurance Section) and instructions for electronic record keeping are described in detail and include network path addresses.
- Region 4 maintains excellent records. While the region continues to transition to electronic record keeping, the region is encouraged to file MOAs, MOUs, and other contractual documents with the respective state, ensure these agreements are available

and accessible. TSC recommends that Region 4 include all labs and programs in one continuously updated worksheet such that all labs (including satellite labs) are captured. The satellite lab references should include official names or EPA Lab IDs such that PTs are easier to track.

5. Communication and Technical Assistance

The regions' oversight of the certification programs includes providing technical assistance to the states. As stated in the MCLADW, the region's responsibilities include, "(sponsoring) annual meetings for the State COs and (providing) technical assistance to the States' EPA-certified drinking water laboratories, as needed." This section reviews the regions' performance of these tasks.

a. Regional Communication

- Record keeping of communications between the region and states regarding SLCPAs or PSL audits are updated weekly in great detail in a spreadsheet.
- The RLCP meets quarterly with the Regional Drinking Water Program staff to discuss implementation issues.
- As suggested in the MCLADW, the region usually hosts annual meetings with all of the states/territories under their purview to foster an atmosphere of collaboration and communication. Due to the 2013 furlough and changes in laboratory management, two annual meetings were missed. The 2015 annual meeting coincided with this RLCPA, and the region is back on track to continue annual meetings. Agendas from previous meetings are retained as documentation.

b. Regional Technical Assistance

- The region provides technical assistance to the states' EPA-certified drinking water laboratories, and responds to requests for clarification for method interpretation. The region documents all communication with states in a spreadsheet updated weekly, recording the CO who has made the entry and the topic of discussion.

Attachment A

Agenda: EPA Region 4 Laboratory Certification Program Assessment

Time/Date	Topic	Location	Invitees
Tuesday Oct. 20, 2015			
9:00 AM – 3:00 PM	Michella, Judy, and Erina travel to Athens, GA		
3:00 PM – 4:00 PM	Michella and Judy arrive at regional office and prepare to present at the Region 4 States Annual Laboratory Meeting		
4:00 PM – 5:00 PM	Present drinking water program update to regional/state COs	TBD	Regional/state COs and interested GWDWB staff
Wednesday Oct. 21, 2015			
9:00 AM – 10:00 AM	Opening Conference	TBD	Michella, Judy, Erina, Ray Terhune, regional COs
10:00 AM – 12:00 PM	Region 4 file review	TBD	Michella, Judy, Erina
12:00 PM – 1:00 PM	Lunch		
1:00 PM – 4:30 PM	Region 4 file review	TBD	Michella, Judy, Erina
Thursday Oct. 22, 2015			
9:00 AM – 12:00 PM	Continue Region 4 file review	TBD	Michella, Judy, Erina
12:00 PM – 1:00 PM	Lunch		
1:00 PM – 3:30 PM	Finish Region 4 file review and compile notes for closing meeting	TBD	Michella, Judy, Erina
3:30 PM – 4:30 PM	Closing conference	TBD	Michella, Judy, Erina, Ray Terhune, Bobbi Carter, Antonio Quinones

Attachment B**Attendees at Meetings for the October 2015 EPA Region 4 RLCPA**

	Participant	Program	Role	Meeting
1.	Judith Brisbin	US EPA	TSC Lead Assessor	All
2.	Michella Karapondo	US EPA	TSC Assessment Team	All
3.	K. Erina Keefe	US EPA	Contractor - Cadmus	All
4.	Ray Terhune	US EPA Region 4	Acting OQA LCPM	All
5.	John Thomason	US EPA Region 4	Regional CO	Opening conference
6.	Viola Reynolds	US EPA Region 4	Regional CO	Opening conference
7.	Nancy Seabolt	US EPA Region 4	Regional CO	Opening conference
8.	Sandra Aker	US EPA Region 4	Regional CO	Opening conference
9.	Jeff Wilmoth	US EPA Region 4	Regional CO	Opening conference
10.	Bobbi Carter	US EPA Region 4	Regional QA Manager	Closing conference
11.	Antonio Quinones	US EPA Region 4	Deputy Director	Closing conference

Attachment C

EPA Region 4 Laboratory Certification Program Organizational Chart

Science and Ecosystem Support Division Athens, Georgia

